

(2) As substitutes for the corresponding naturally derived fatty alcohols used as intermediates in the synthesis of food additives and other substances permitted in food.

[42 FR 14491, Mar. 15, 1977, as amended at 47 FR 11837, Mar. 19, 1982; 49 FR 10105, Mar. 19, 1984; 54 FR 24897, June 12, 1989]

§ 172.866 Synthetic glycerin produced by the hydrogenolysis of carbohydrates.

Synthetic glycerin produced by the hydrogenolysis of carbohydrates may be safely used in food, subject to the provisions of this section:

(a) It shall contain not in excess of 0.2 percent by weight of a mixture of butanetriols.

(b) It is used or intended for use in an amount not to exceed that reasonably required to produce its intended effect.

§ 172.867 Olestra.

Olestra, as identified in this section, may be safely used in accordance with the following conditions:

(a) Olestra is a mixture of octa-, hepta-, and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms.

(b) Olestra meets the following specifications:

(1) The total content of octa-, hepta-, and hexa-esters is not less than 97 percent as determined by a method entitled "Determination of Olestra by Size Exclusion Chromatography," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(2) The content of octa-ester is not less than 70 percent as determined by a method entitled "Measurement of the

Relative Ester Distribution of Olestra Test Material" dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(3) The content of hexa-ester is not more than 1 percent as determined by the method listed in paragraph (b)(2) of this section.

(4) The content of penta-ester is not more than 0.5 percent as determined by the method listed in paragraph (b)(2) of this section.

(5) The unsaturated fatty acid content is not less than 25 percent (thus not more than 75 percent saturated fatty acid) and not more than 83 percent as determined by a method entitled "Measurement of the Fatty Acid Composition of Olestra Test Material," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(6) The content of C12 and C14 fatty acids is each not more than 1 percent, and total C20 and longer fatty acids is not more than 20 percent. C16 and C18 fatty acids make up the remainder with total content not less than 78 percent as determined by the method listed in paragraph (b)(5) of this section.

(7) The free fatty acid content is not more than 0.5 percent as determined by a method entitled "Free Fatty Acids" published in the *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 3d Ed. (1985) vol. 1,

which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(8) The residue on ignition (sulfated ash) is not more than 0.5 percent.

(9) Total methanol content is not more than 300 parts per million as determined by the "Total Available Methanol Method," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(10) The total heavy metal content (as Pb) is not more than 10 parts per million.

(11) Lead is not more than 0.1 part per million, as determined by a method entitled "Atomic Absorption Spectrophotometric Graphite Furnace Method," Food Chemicals Codex, 3d Ed. 3d Supp. p. 168 (1992), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Research Council Press, 2101 Constitution Ave. NW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(12) Water is not more than 0.1 percent, as determined by a method entitled "Moisture," *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989), vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society,

1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(13) Peroxide value is not more than 10 meq/kg as determined by a method entitled "Peroxide Value," *Official Methods and Recommended Practices of the American Oil Chemists' Society*, 4th Ed. (1989) vol. 1, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists Society, 1608 Broadmoor Dr., Champaign, IL 61821, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(14) The stiffness is not less than 50 kiloPascals/second, as determined by a method entitled "Method for Measurement of the Stiffness of Olestra," dated December 19, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 200 C St. SW., Washington, DC, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors.

(d) To compensate for any interference with absorption of fat soluble vitamins, the following vitamins shall be added to foods containing olestra: 1.9 milligrams alpha-tocopherol equivalents per gram olestra; 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate); 12

IU vitamin D per gram olestra; and 8 µg vitamin K₁ per gram olestra.

(e)(1) The label of a food containing olestra shall bear the following statement in the manner prescribed in paragraph (e)(2) of this section:

THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.

(2) The statement required by paragraph (e)(1) of this section shall:

(i) Appear either on the principal display panel or on the information panel of the label;

(ii) Be enclosed by a 0.5 point box rule with 2.5 points of space around the statement.

(iii) Utilize at least one point leading;

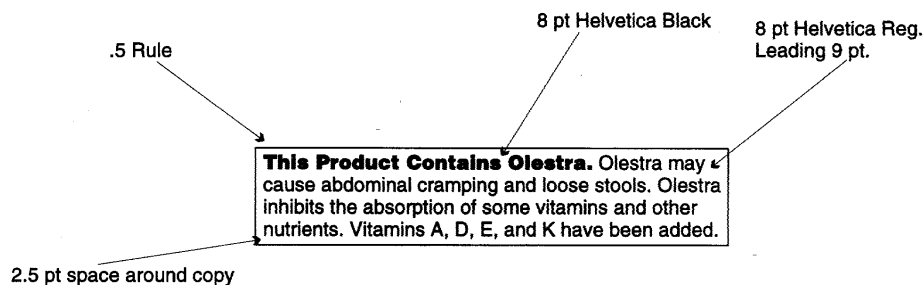
(iv) Have type that is kerned so the letters do not touch;

(v) Be all black or one color type, printed on a white or other neutral contrasting background whenever possible;

(vi) Utilize a single easy-to-read type style such as Helvetica Regular and upper and lower case letters; and

(vii) Be in type size no smaller than 8 point.

(3) The sentence "This Product Contains Olestra." shall be highlighted by bold or extra bold type, such as Helvetica Black. The label shall appear as follows:



(4) Vitamins A, D, E, and K present in foods as a result of the requirement in paragraph (d) of this section shall be declared in the listing of ingredients. Such vitamins shall not be considered in determining nutrient content for the nutritional label or for any nutrient claims, express or implied.

(5) Olestra shall not be considered as a source of fat or calories for purposes of §§101.9 and 101.13 of this chapter.

(f) Consistent with its obligation to monitor the safety of all additives in the food supply, including olestra, the Food and Drug Administration will review and evaluate all data and information bearing on the safety of olestra received by the agency after the effective date of this regulation, and will present such data, information, and evaluation to the agency's Food Advisory Committee within 30 months of the effective date of this regulation.

The purpose of such presentation will be to receive advice from the Committee on whether there continues to be reasonable certainty that use of olestra in compliance with this regulation is not harmful. The agency will hold such additional Food Advisory Committee meetings on olestra as the agency determines, in its discretion, to be necessary. Based upon the results of this entire process, the FDA will initiate any appropriate regulatory proceedings.

[61 FR 3171, Jan. 30, 1996; 61 FR 11546, Mar. 21, 1996]

§ 172.868 Ethyl cellulose.

The food additive ethyl cellulose may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is a cellulose ether containing ethoxy (OC₂H₅) groups